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EXAMINER	
WESTERBERG, NISSA M	
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1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,809	AVRAMOFF ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *1 - 6, 8, 10 - 16, 18, 20, 21, 23 - 25, 51 - 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 - 32, 34, 36 - 42, 44, 46, 47, 49, 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1 - 6, 8, 10 - 16, 18, 20, 21, 23 - 32, 34, 36 - 42, 44, 46, 47, 49 - 57.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group II and a composition in which the lansoprazole containing portion of the dosage form does not include an alkaline agent in the reply filed on April 28, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

In the conclusion to the response, Applicant requests rejoinder of group I with group II if the restriction requirement between the two groups is upheld by the Examiner. Since Applicant has elected the method claims (group II), this application not eligible for rejoinder of composition claims (group I) should the method claims be found allowable. If the composition claims of group I had been elected, upon indication that the product claims were allowable, the withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim would have been considered for rejoinder.

Claim Rejections - 35 USC § 112 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It unclear what grade(s) of lactose are encompassed by the limitation “a suitable grade of lactose” and/or what properties of lactose would cause it to be of an unsuitable grade.

4. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “at least one of sodium stearate" concludes the claim. “At least one of” generally introduces a Markush group but the list of items to be chosen from is only one. Therefore it is unclear whether Applicant wished to name other organic basic salts or if claim 40 was intended to be that the organic basic salt is sodium stearate.

5. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 recites the limitation "said active coating" in lines 1 – 2. There is insufficient antecedent basis for this limitation in the claim as it depends from claim 27 and not claim 29, in which the substrate is defined as comprising a neutral core and an active coating. It is also unclear how claims 44 and 34 differ, as both require the active coating to comprise at least one surfactant selected from the group consisting of Tween® 80 and sodium lauryl sulfate.

6. Claims 34 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims contain the trademark/trade name Tween® 80. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polysorbate 80 and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 27 – 32, 38, 39, 42, 46, 47, 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Depui et al. (WO 96/24375).

WO'375 discloses an oral, enteric coated dosage form comprising an acid labile proton pump inhibitor (PPI) useful in the treatment of disorders associated with *Heliobacter* infections (abstract). In examples 8 (beginning of p 28) and 11 (beginning on page 39), a multilayer dosage form comprising lansoprazole (in the free base form, not as a pharmaceutically acceptable salt) are prepared. The core contains a sugar sphere seed (non-pareil neutral core) coated with lansoprazole, the cellulosic polymer hydroxypropyl methyl cellulose (HPMC) and water (aqueous solvent). The size of the core can vary between 0.1 – 2 mm (p 13, ln 13 – 14). No alkaline material is present in the core. The separating layer (subcoating layer of the instant claims) comprises the cellulosic polymer hydroxypropyl cellulose, the filler talc, the alkaline agent magnesium stearate and the solvent water. An enteric coating layer comprising a methacrylic acid copolymer and the plasticizer triethyl citrate (a citric acid ester) is present in the dosage form.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 27 – 32, 34, 36 – 39, 42, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al (WO 96/24375).

WO'375 discloses an oral, enteric coated dosage form comprising an acid labile proton pump inhibitor useful in the treatment of disorders associated with *Heliobacter* infections (abstract). In examples 8 (beginning of p 28) and 11 (beginning on page 39), a multilayer dosage form comprising lansoprazole (in the free base form, not as a

pharmaceutically acceptable salt) are prepared. The core contains a sugar sphere seed (neutral core) coated with lansoprazole, the cellulosic polymer hydroxypropyl methyl cellulose (HPMC) and water (aqueous solvent). No alkaline material is present in the core. The size of the core can vary between 0.1 – 2 mm (p 13, ln 13 – 14). The separating layer (subcoating layer of the instant claims) comprises the cellulosic polymer hydroxypropyl cellulose, the filler talc, the alkaline agent magnesium stearate and the solvent water. An enteric coating layer comprising a methacrylic acid copolymer and the plasticizer triethyl citrate (a citric acid ester) is present in the dosage form. The active ingredient can be mixed with other ingredients such as binders, surfactants and fillers (p 13, ln 18 – 26). In example 18 (beginning on page 46), the surfactant sodium lauryl sulfate and the filler anhydrous lactose are included in the same layer as the active ingredient (omeprazole).

WO'375 does not have an example in which a surfactant such as sodium lauryl sulfate and the filler lactose are present in the same layer as the active ingredient.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a lansoprazole dosage form and administer that dosage form orally as WO'375 discloses that such ingredients may be added to the composition and prepares such a composition using the functionally equivalent therapeutic agent omeprazole.

13. Claims 26 – 32, 34, 36 – 39, 42, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO'375 as applied to claims 27 – 32, 34, 36

– 39, 42, 46, 47, 49 and 50 above, and further in view of Lundberg et al. (EP 1 174 136).

WO'375 discloses a multilayer oral lansoprazole dosage form with multiple layers – a neutral core coated with lansoprazole and various excipients, an intermediate or subcoating layer comprising an alkaline agent and various excipients and an enteric coating layer, which may be used in the treatment of gastrointestinal conditions by administration of the dosage form. For the lansoprazole formulations, the separating (subcoating) layer comprises a cellulosic polymer, filler, alkaline agent and a solvent.

WO'375 does not disclose the inclusion of a surfactant in the subcoating layer.

Lundberg et al. discloses similar trilayer (active ingredient core, intermediate layer and enteric layer) proton pump inhibitor containing pharmaceutical compositions. In example 1 (beginning on p 9), a separating layer comprising talc (filler), sodium dodecyl sulfate (surfactant), microcrystalline cellulose (cellulosic polymer) and magnesium stearate (alkaline agent) is disclosed. These ingredients are mixed with granulated active ingredient and no solvent is present.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a surfactant in the subcoating layer, taught by Lundberg et al. as a suitable composition for an intermediate layer in trilayer PPI dosage forms, and to apply this layer in a liquid fashion using a solvent, a method taught by WO'375 as suitable for application of the subcoating layer to active ingredient containing cores which are then further coated with an enteric layer.

Applicant has not defined what additional components in the subcoating layer defined in claim 26 would materially affect the basic and novel characteristics of the in invention. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) **MPEP 2111.03**

14. Claims 27 – 32, 34, 36 – 40, 42, 46, 47, 49 and 50 rejected under 35 U.S.C. 103(a) as being unpatentable over WO'375 as applied to claims 27 – 32, 34, 36 – 39, 42, 46, 47, 49 and 50 above, and further in view of Edgren et al. (US 6,210,712).

WO'375 discloses a multilayer oral lansoprazole dosage form with multiple layers – a neutral core coated with lansoprazole and various excipients, an intermediate or subcoating layer comprising an alkaline agent and various excipients and an enteric

coating layer, which may be used in the treatment of gastrointestinal conditions by administration of the dosage form. For the lansoprazole formulations, the separating (subcoating) layer comprises a cellulosic polymer, filler, the alkaline agent magnesium stearate and a solvent.

WO'375 does not disclose the inclusion of sodium stearate in the subcoating layer.

Edgren et al. discloses that potassium stearate, magnesium stearate and sodium stearate are functionally equivalent (col 8, ln 6 – 10).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a multilayer lansoprazole dosage for oral administration to patients, as taught in WO'375, and to replace the magnesium stearate in the subcoating layer with the functionally equivalent sodium stearate, taught by Engren et al.

15. Claims 27 – 32, 34, 36 – 39, 41, 42, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO'375 as applied to claims 27 – 32, 34, 36 – 39, 42, 46, 47, 49 and 50 above, and further in view of Depui et al. (US 2002/0155153).

WO'375 discloses a multilayer oral lansoprazole dosage form with multiple layers – a neutral core coated with lansoprazole and various excipients, an intermediate or subcoating layer comprising an alkaline agent and various excipients and an enteric coating layer, which may be used in the treatment of gastrointestinal conditions by administration of the dosage form. For the lansoprazole formulations, the separating

(subcoating) layer comprises a cellulosic polymer, filler, the alkaline agent magnesium stearate and a solvent.

WO'375 does not disclose the inclusion of an inorganic basic salts in the subcoating layer or Tween® 80 or sodium lauryl sulfate in the active ingredient layer.

US'153 discloses that the optional separating layer, between the core containing the proton pump inhibitor active ingredient and enteric coating layer (see figures 3 and 5), can contain pH buffering agents such as the inorganic salts generally used as antacids (for example, aluminum or calcium hydroxide, carbonate or silicate; or magnesium oxide, carbonate or silicate), weak inorganic acids such as citric acid or suitable organic bases such as the basic amino acids (paragraph [0062]). In example 4 (paragraph [0109]), the non-pareil coating layer comprises water, sodium lauryl sulfate, lansoprazole and HPMC.

It would have been obvious to one of ordinary skill to replace the alkaline magnesium stearate in the subcoating layer of the dosage form administered by WO'375 with an inorganic basic salt, taught by US'153 as suitable alkaline agents that improve the pH-buffering capacity of the subcoating layer. It also would have been obvious to add sodium lauryl sulfate to the lansoprazole containing layer as such a layer composition is disclosed by US'153.

16. Claims 26 – 32, 34, 36, 38, 39, 41, 42, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (US 2002/0155153).

In example 4 (paragraph [0109]), enteric coated tablets of lansoprazole are prepared. The core consists of non-pareil cores coated with water, the surfactant sodium lauryl sulfate, lansoprazole and the cellulosic polymer HPMC. A subcoating layer comprised of water and ethanol as solvents, the filler talc, the surfactant polyethylene glycol 6000 (PEG 6000) and the cellulosic polymer HPMC is applied. Then an enteric coating of hydroxypropoly methylcellulose phthalate, the plasticizers acetyltributyl citrate and cetanol (cetyl alcohol) is applied to the pellets.

The separating layer may serve as a diffusion barrier and pH-buffering zone (paragraph [0062]). To strengthen the buffering capacity of this layer, substance such as the inorganic salts generally used as antacids (for example, aluminum or calcium hydroxide, carbonate or silicate; or magnesium oxide, carbonate or silicate), weak inorganic acids such as citric acid or suitable organic bases such as the basic amino acids (paragraph [0062]).

The enteric coating layer can be comprised of a number of materials, including methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate phthalate and cellulose acetate trimellitate (paragraph [0064]). The enteric layer may also contain pharmaceutically acceptable plasticizers such as citric acid esters, phthalic acid esters, cetyl alchol and polysorbates (paragraph [0065]).

These dosage forms are administered one to several times a day to treat gastrointestinal side effects caused by NSAIDs (non-steroidal anti-inflammatory drugs; paragraph [0087]).

US'153 does not explicitly disclose a lansoprazole preparation in which an inorganic or organic basic salt is present in the separating layer.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a multilayer lansoprazole oral dosage for administration as taught by US'153 and to include an alkaline agent, such as a basic amino acid or carlcium carbonate in the separating layer, as the inclusion of such compounds in the separating layer is taught to improve the pH-buffering capacity of this layer.

Applicant has not defined what additional components in the subcoating layer defined in claim 26 would materially affect the basic and novel characteristics of the in invention. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) **MPEP 2111.03**

17. Claims 26 – 32, 34, 36, 38, 39, 41, 42, 44, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US'153 as applied to claims 26 – 32, 34, 36, 38, 39, 41, 42, 46, 47, 49 and 50 above, and further in view of Lundberg et al.

US'153 discloses a multilayer lansoprazole oral dosage form with a neutral core, a subcoating layer and an enteric coating layer. Various excipients may be present in each of these layers.

US '153 does not disclose the inclusion of a Tween® 80 or sodium lauryl sulfate in the subcoating layer.

Lundberg et al. discloses similar trilayer (active ingredient core, intermediate layer and enteric layer) proton pump inhibitor containing compounds. In example 1 (beginning on p 9), a separating layer comprising talc (filler), sodium dodecyl sulfate (surfactant), microcrystalline cellulose (cellulosic polymer) and magnesium stearate rate (alkaline agent) is added. These ingredients are mixed with granulated active ingredient and no solvent is present. Disclosed pharmaceutically acceptable surfactants includes non-ionic and ionic surfactants such as sodium lauryl sulfate or polysorbates (Tween® products; paragraph [0032]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include sodium lauryl sulfate or a polysorbate, taught by Lundberg et al. as pharmaceutically acceptable surfactants and therefore functionally equivalent to the PEG 6000 present in the subcoating layer of the dosage form taught by US'153.

18. Claims 26 – 32, 34, 36, 38 – 42, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US'153 as applied to claims 26 – 32, 34, 36, 38, 39, 41, 42, 46, 47, 49 and 50 above, and further in view of Edgren et al. (US 6,210,712).

US'153 discloses a multilayer lansoprazole oral dosage form with a neutral core, a subcoating layer and an enteric coating layer. Various excipients may be present in each of these layers.

US '153 does not disclose the inclusion of sodium stearate in the subcoating layer.

Edgren et al. discloses potassium stearate, magnesium stearate and sodium stearate are functionally equivalent (col 8, ln 6 – 10).

It would have been obvious to one of ordinary skill in the art at the time of the instant to prepare a multilayer lansoprazole dosage for oral administration to patients, as taught in US'153, and to replace the magnesium stearate in the subcoating layer with the functionally equivalent sodium stearate, taught by Engren et al.

19. Claims 26 – 32, 34, 36 – 39, 41, 42, 44, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US'153 as applied to claims 26 – 32, 34, 36, 38, 39, 41, 42, 46, 47, 49 and 50 above, and further in view of WO'375.

US'153 discloses a multilayer lansoprazole oral dosage form with a neutral core, a subcoating layer and an enteric coating layer. Various excipients may be present in each of these layers.

US '153 does not disclose the inclusion of the filler lactose in the active coating.

WO'375 discloses a pharmaceutical composition of omperazole in which the portion of the dosage form with the active ingredient includes the filler lactose (p 46).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a multilayer lansoprazole dosage form for oral administration to patients as taught in US'153, and to include a lactose filler in the active coating layer, as WO'375 teaches that lactose is a suitable excipient in the active ingredient containing portion of the trilayer PPI dosage form.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW